UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,674	10/23/2001	M. Michael Wolfe	50128/002003	8781

21559 7590 05/03/2004

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
ROMEO, DAVID S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/003,674	WOLFE ET AL.	
	Examiner	Art Unit	
	David S Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06/13/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-35 are pending.

Applicant's election without traverse of group I, claims 1-34, in Paper No./the paper filed 02/09/2004 is acknowledged.

Applicant's election without traverse of the species SEQ ID NO: 2 in Paper No./the paper filed 02/09/2004 is acknowledged.

Applicant's election with traverse of the species "dispersing" and "normal saline" in Paper No./the paper filed 02/09/2004 is acknowledged. The traversal is on the ground(s) that a search of these embodiments would not impose an unreasonable or undue burden. This is not found persuasive because election of species should be required prior to a search on the merits (A) in all applications containing claims to a plurality of species with no generic claims, and (B) in all applications containing both species claims and generic or Markush claims. Contrary to Applicants' assertion, the species are independent and distinct, wherein one is not required for the production or use of any of the others, wherein one can be manufactured independently of any of the others, and wherein a search of one is not required or co-extensive with a search of any of the others. Therefore, a search of all these embodiments would impose an unreasonable or undue burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8 and 10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), to the extent that they are drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No./the paper filed 02/09/2004.

Claim 35 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No./the paper filed 02/09/2004.

Claims 1-34 are being examined to the extent that they are drawn to or encompass the species SEQ ID NO: 2, dispersing, and normal saline.

Specification

The disclosure is objected to because of the following informalities: in the preliminary amendment filed 03/05/2002 the date December 12, 1996 should be December 3, 1996.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4, 6, 7, 11-14, 16, 18, 20, 22, 24, 26, 28, 30, 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear if the phrase "corresponding to" should be interpreted narrowly to encompass only materials that have a structure identical to a referenced GIP sequence or if the phrase should be interpreted broadly to encompass materials which have a structure "similar" to a referenced GIP sequence. The metes and bounds are not clearly set forth.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 27 is indefinite over the recitation of "comprises 21 amino acids in positions 21-30" because positions 21-30 do not amount to 21 amino acids. The metes and bounds are not clearly set forth.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 is indefinite over the recitation of "posts 7-30" because the term "posts" is not an art accepted term for designating an amino acid sequence and the meaning of the term is not clearly set forth. The metes and bounds are not clearly set forth.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear if the claim is directed to the product or to the process of reconstitution. A single claim which claims both a product and the method steps of using the product is indefinite under 35 U.S.C. 112, second paragraph. The metes and bounds are not clearly set forth. See M.P.E.P. § 2173.05(p).

Claims 3, 6, 11, 13, 16, 18, 20, 22, 24, 26, 28, 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite because it is unclear what amino acids and/or effect is intended by an "at least an effective number." In the absence of a recitation as to any effect it is unclear what amino acids and/or effect can be inferred. The metes and bounds are not clearly set forth.

Claims 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 30 is indefinite over the recitation of "amino acids in positions 31-44 of the sequence of rat GIP, SEQ ID NO: 13" because "positions 31-44" amount to 14 amino acids, SEQ ID NO: 13 is amino acids 21-30 of rat GIP and not "positions 31-44," amino acids 21-30 of rat GIP amount to 10 amino acids, and 10 amino acids do not amount to "positions 31-44" or 14 amino acids. The metes and bounds are not clearly set forth.

Claims 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 31 is indefinite over the recitation of "comprises 14 amino acids in positions 31-44 of the sequence of rat GIP, SEQ ID NO: 13" because "positions 31-44" amount to 14 amino acids, SEQ ID NO: 13 is amino acids 21-30 of rat GIP and not "positions 31-44," amino acids 21-30 of rat GIP amount to 10 amino acids, and 10 amino acids do not amount to "positions 31-44" or 14 amino acids. The metes and bounds are not clearly set forth.

Claims 15-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 15-34 are indefinite over the recitation of "specifically interferes" in claims 15 and 32. Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "specifically interferes" an artisan cannot determine what additional or material functional limitations are placed upon a claim by the presence of this element.

Claims 1-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a GIP antagonist comprising amino acids 7-30 or 10-30 of GIP, does not reasonably provide enablement for a GIP antagonist "corresponding to" a referenced GIP sequence, a GIP antagonist comprising an "effective

number" of amino acids "corresponding to" a referenced GIP sequence, a GIP antagonist or GIP antagonistic polypeptide without regard to the structure thereof, a GIP antagonist comprising "effective alternative sequences," or a GIP antagonist comprising positions 16-30, 21-30, 31-44, or 7-9 of a GIP. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

A GIP antagonist according to the present specification is any composition which interferes with biological action of GIP (page 6, last full paragraph). The present specification contemplates any polypeptide sequence which effectively prevents GIP activation of its native receptor, such as the sequence containing amino acids in positions 7-30 of the sequence of the GIP sequence and polypeptides based upon sequences containing amino acids in positions 7-30 of the sequence of the GIP that include additional, deleted or alternative amino acids to form effective GIP polypeptide antagonist. Polypeptides based on this sequence may be designed for use as GIP antagonists according to this invention by the skilled artisan, who will routinely confirm that the resultant peptides exhibit antagonist function by testing the peptides in in vitro and in vivo assays. Page 7, lines 14-22. GIP (7-30)-NH_2, GIP (16-3 0)-NH_2, GIP (21-30)-NH_2, and GIP (31-44) were examined to determine whether any of these fragments might serve as an antagonist to GIP. Only GIP (7-30)-NH_2 (ANTIGIP) was found to attenuate the cAMP stimulatory effects exhibited by GIP (1-42). Page 13, full paragraph 1. Peptide GIP (10-30)-NH_2 is an antagonist, albeit a weak one. On the other hand, GIP (10-30)-NH_2 also has agonist properties. Page 13, full paragraph 2. Peptide antagonists

would appear to require the segment from amino acids 7-9 of the GIP sequence, and some or all of the amino acids from 10-30 (page 7, lines 11-13).

The instant specification clearly contemplates GIP sequences that include additional, deleted or alternative amino acids (page 7, lines 14-19). GIP antagonists that "correspond to" a referenced GIP sequence are interpreted to include additional, deleted or alternative amino acids thereto. GIP antagonists that are effective alternative sequences to a referenced GIP sequence are interpreted to include additional, deleted or alternative amino acids thereto. GIP antagonist that comprise "at least an effective number" of unspecified and indeterminate amino acid residues "corresponding to" a referenced GIP sequence are interpreted to include additional, deleted or alternative amino acids thereto. The specification has only shown that peptides comprising amino acids 7-30 or 10-30 of GIP have GIP antagonistic activity. Other than amino acids 7-30 or 10-30 of GIP, the specification has not shown that any of the other referenced GIP sequences have antagonistic activity. Moreover, the specification teaches that the peptide antagonists would appear to require amino acids 7-9 and some or all amino acids 10-30. The specification does not provide a reasonable expectation that peptides other than amino acids 7-30 or 10-30 would have the required activity, which indicates that the number of inoperable embodiments exceeds the operable ones. The skilled artisan is left to extensive experimentation wherein GIP sequences, other than amino acids 7-30 or 10-30 of GIP, are randomly modified and/or added thereto and through trial and experimentation is left to determine which peptides are GIP antagonists. A skilled practitioner would also have to resort to a substantial amount of undue experimentation in the form of random, trial and error experimentation of any and/or all compounds or

peptides. Such extensive, random, trial and error experimentation is considered undue. Moreover, there is a lack of predictability in the art. Predicting structure, hence function, from primary amino acid sequence data is extremely complex and there doesn't exist an efficient algorithm for predicting the structure of a given protein from its amino acid sequence alone. See Bowie (U) page 1306, column 1, full paragraph 1, or Ngo (V) page 433, full paragraph 1, and page 492, full paragraph 2.

The current claim limitations are analogous to those of claim 7 of U.S. Patent No. 4,703,008, which were held to be invalid under 35 U.S.C. § 112, first paragraph, for want of enablement in Amgen Inc. v. Chugai Pharmaceuticals Co. Ltd., 18 USPQ 2d, 1016 (CAFC, 3/5/91, see page 1026, section D). In that instance a claim to a nucleic acid molecule encoding a polypeptide having an amino acid sequence sufficiently duplicative of the amino acid sequence of erythropoietin (EPO) so as to have a specified biological activity was held to be invalid under 35 U.S.C. § 112, first paragraph, for want of enablement. This limitation is analogous to the "corresponding to," "effective number," and "effective alternative sequences thereto" limitations of the present claims. The disclosure upon which that claim was based described a recombinant DNA encoding EPO and a few analogs thereof. That disclosure differs from the instant specification because, whereas the instant specification describes a single antagonist with a natural amino acid sequence, it does not describe even a single effective alternative sequence thereto. The court held that what is necessary to support claims of this breadth is a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of the claims. That means disclosing how to make and use enough sequences to justify the grant of the patent protection sought in the instant claims.

The instant specification is even more limited that the '008 patent because it describes only a naturally occurring amino acid sequence and no effective alternative sequences thereto and, therefore, provides even less support that the '008 specification for claims of comparable scope and which were held to be invalid in that patent.

In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, the unpredictability in the art and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and use the full scope of the claimed invention.

Claims 5-8, 13, 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing glucose adsorption, does not reasonably provide enablement for preventing, inhibiting, or reducing obesity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to a pharmaceutical composition for preventing, inhibiting, or reducing obesity, which requires that the composition be able to so perform. The specification teaches that ANTIGIP reduced intestinal glucose adsorption (Example 6). However, neither the specification nor the prior art of record establishes a nexus between this activity and preventing, inhibiting, or reducing obesity. Furthermore, Marx (W) states that few "medical problems have proved to be more intractable than obesity;" the condition is frustratingly hard to treat (page 1477, column 1, full paragraph 1). Woods (X) teaches that although satiety peptides can alter the size of individual meals, their

repeated administration does not alter body weight and has limited influence on adiposity (page 1379, column 1, full paragraph 2). The specification fails to disclose specific guidance for administering a GIP antagonist and thereby preventing, inhibiting, or reducing obesity. There are no working examples of preventing, inhibiting, or reducing obesity. In view of the intractable nature and unpredictability of treating obesity and the lack of guidance with respect to dosages and the lack of working examples, one skilled in the art could not use claimed pharmaceutical composition for preventing, inhibiting, or reducing obesity without undue experimentation.

Claims 1-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to or encompass a GIP antagonist "corresponding to" a referenced GIP sequence, a GIP antagonist comprising an "effective number" of amino acids "corresponding to" a referenced GIP sequence, a GIP antagonist or GIP antagonistic polypeptide without regard to the structure thereof, a GIP antagonist comprising "effective alternative sequences," or a GIP antagonist that comprises "at least an effective number" of unspecified and indeterminate amino acid residues of a referenced GIP sequence. The claims are directed to a genus of compounds that are antagonists of GIP.

A GIP antagonist according to the present specification is any composition which interferes with biological action of GIP (page 6, last full paragraph). The present specification contemplates any polypeptide sequence which effectively prevents GIP activation of its native receptor, such as the sequence containing amino acids in positions 7-30 of the sequence of the GIP sequence and polypeptides based upon sequences containing amino acids in positions 7-30 of the sequence of the GIP that include additional, deleted or alternative amino acids to form effective GIP polypeptide antagonist. Polypeptides based on this sequence may be designed for use as GIP antagonists according to this invention by the skilled artisan, who will routinely confirm that the resultant peptides exhibit antagonist function by testing the peptides in in vitro and in vivo assays. Page 7, lines 14-22. GIP (7-30)-NH_2, GIP (16-3 0)-NH_2, GIP (21-30)-NH_2, and GIP (31-44) were examined to determine whether any of these fragments might serve as an antagonist to GIP. Only GIP (7-30)-NH_2 (ANTIGIP) was found to attenuate the cAMP stimulatory effects exhibited by GIP (1-42). Page 13, full paragraph 1. Peptide GIP (10-30)-NH_2 is an antagonist, albeit a weak one. On the other hand, GIP (10-30)-NH_2 also has agonist properties. Page 13, full paragraph 2. Peptide antagonists would appear to require the segment from amino acids 7-9 of the GIP sequence, and some or all of the amino acids from 10-30 (page 7, lines 11-13).

The specification and claim do not indicate what distinguishing attributes shared by the members of the genus. The specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to a referenced GIP sequence. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of

structural differences between genus members is permitted. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, GIP (7-30)-NH_2 and GIP (10-30)-NH_2 alone are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 10 is directed to a product and a process of reconstituting the product. Claim 10 is rejected under 35 U.S.C. 101 based on the theory that the claim is directed to neither a "process" nor a "composition of matter," but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. See M.P.E.P. § 2173.05(p).

Double Patenting

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-34 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 8-16, 18-41 of copending Application No. 08/984,476. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Application No. 08/984,476 is in the process of being converted from a paper file to an electronic file and is currently unavailable to the examiner. This rejection is based on the examiner's copy of the claims in Application No. 08/984,476, which appear to be identical to the claims of the present application. This rejection is applicable to any newly submitted or amended claims filed with the RCE in the copending application, to the extent that Applicants are claiming the same invention as that of any newly submitted or amended claims filed with the RCE in copending Application No. 08/984,476.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

Claims 1-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8-16, 18-41 of copending Application No. 08/984,476. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the

present application are generic to and fully encompass the claims of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Application No. 08/984,476 is in the process of being converted from a paper file to an electronic file and is currently unavailable to the examiner. This rejection is based on the examiner's copy of the claims in Application No. 08/984,476. Applicants are claiming the same or similar compounds with the same activity. This rejection is applicable to any newly submitted or amended claims filed with the RCE in the copending application, to the extent that the claims of the present application are generic to and fully encompass any newly submitted or amended claims filed with the RCE in the copending application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-8, 11, 13-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Ebert (Y).

Ebert teaches a specific GIP antiserum (page 1601, paragraph bridging columns 1-2). The antiserum comprises an antibody or antibodies that is or are an antagonist of

GIP, and that comprises an effective alternative sequence to a referenced GIP sequence. Ebert also teaches a pharmaceutical composition comprising the anti-GIP, antagonistic antibody or antibodies (page 1602, columns 1-2). The antiserum is a dispersing agent in the absence of evidence to the contrary.

Claims 20-23, 27-32 are rejected under 35 U.S.C. 102(a) as being anticipated by Gelling (VV).

Under 35 U.S.C. 120, the claims in a U.S. application are entitled to the benefit of the filing date of an earlier filed U.S. application if the subject matter of the claim is disclosed in the manner provided by 35 U.S.C. 112, first paragraph in the earlier filed application.

Under 35 U.S.C. 119 (e), the claims in a U.S. application are entitled to the benefit of the filing date of a provisional application if the corresponding provisional application supports the claims in the manner required by 35 U.S.C. 112, first paragraph.

The 08/984,476 and 60/032,329 parent applications do not describe a GIP antagonist comprising amino acids 16-30, 21-30, 31-44, or 7-9 of GIP. Therefore, the subject matter of claims 20-23, 27-32 is not entitled to the to the benefit of the filing dates of any of the earlier filed applications.

Gelling teaches porcine $GIP_{10\text{-}30,\ 6\text{-}30,\ 7\text{-}30}$ antagonistic peptides (Abstract). Porcine $GIP_{6\text{-}30}$ corresponds to, is an effective alternative sequence to, or comprises an effective number of amino acids corresponding to positions 16-30, 21-30, 31-44, or 7-9 of GIP, human GIP, or rat GIP, SEQ ID NOs: 3, 6, 9, 10, or 13.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim2, 9, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert (Y) in view of Avis (Z) and/or Turco (UU).

Ebert teaches a specific GIP antiserum (page 1601, paragraph bridging columns 1-2). The antiserum comprises an antibody or antibodies that is or are an antagonist of GIP, and that comprises an effective alternative sequence to a referenced GIP sequence. Ebert also teaches a pharmaceutical composition comprising the anti-GIP, antagonistic antibody or antibodies (page 1602, columns 1-2). The antiserum is a dispersing agent in the absence of evidence to the contrary. Ebert is silent with respect to a lyophilized and/or reconstituted GIP antagonist.

Avis teaches that biologics and pharmaceuticals can be stored in the dry state in which there are relatively few stability problems (page 1565, paragraph bridging columns 1-2). Turco teaches that proper electrolyte concentration and balance in plasma and tissues are critical for proper body function and that the electrolytes in normal saline more closely approximate the composition of the extracellular fluid than solutions of any other single salt (page 1570, column 2, bottom). Avis and/or Turco are silent with respect to a lyophilized and/or reconstituted GIP antagonist.

However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to make a GIP antagonist, as taught by Ebert, and to modify that teaching by lyophilizing and/or reconstituting the antagonist, as taught by Avis and/or Turco, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to combine these teachings because there are relatively few stability problems in the dry state and because normal saline more closely approximates the composition of the extracellular fluid than solutions of any other single salt. The invention is prima facie obvious over the prior art.

Claim Objections

Claim 10 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A reconstituted antagonist fails to further limit a lyophilized antagonist.

Conclusion

No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (571) 272-0887.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306
AFTER FINAL (703) 872-9307

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

David Romeo

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
MAY 3, 2004